



Letter Regarding Potential Endo Product Supply Disruption and Possibility of Rare Tablet Mix-Up

January 9, 2012

Dear Pharmacist,

The intent of this letter is to provide you with advance notice of a potential short-term disruption in our supply of the following products:

Strength	Dosage Strength	NDC
OPANA® ER (oxymorphone hydrochloride) Extended-Release Tablets CII	5 mg	63481-907-70
OPANA® ER (oxymorphone hydrochloride) Extended-Release Tablets CII	10 mg	63481-674-70
OPANA® ER (oxymorphone hydrochloride) Extended-Release Tablets CII	20 mg	63481-617-70
OPANA® ER (oxymorphone hydrochloride) Extended-Release Tablets CII	30 mg	63481-571-70
OPANA® ER (oxymorphone hydrochloride) Extended-Release Tablets CII	40 mg	63481-693-70
OPANA® (oxymorphone hydrochloride) Tablets CII	5 mg	63481-612-70
OPANA® (oxymorphone hydrochloride) Tablets CII	10 mg	63481-613-70
Oxymorphone Hydrochloride Tablets CII	5 mg	60951-794-70
Oxymorphone Hydrochloride Tablets CII	10 mg	60951-795-70
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	2.5/325 mg	63481-627-70
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	5/325 mg x 100s	63481-623-70
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	5/325 mg x 500s	63481-623-85
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	7.5/325 mg	63481-628-70
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	7.5/500 mg	63481-621-70
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	10/650 mg	63481-622-70
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	10/325 mg	63481-629-70
PERCODAN® (oxycodone hydrochloride and aspirin, USP) Tablets CII		63481-121-70
ENDOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	7.5/500 mg	60951-796-70
ENDOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	7.5/325 mg	60951-700-70
ENDOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	10/650 mg	60951-797-70
ENDOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	10/325 mg	60951-712-70
ENDOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	5/325mg X 100s	60951-602-70
ENDOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	5/325mg X 500s	60951-602-85
ENDODAN® (oxycodone hydrochloride and aspirin, USP) Tablets CII		60951-310-70
Morphine Sulfate Extended-Release Tablets CII	15 mg	60951-652-70
Morphine Sulfate Extended-Release Tablets CII	30 mg	60951-653-70
Morphine Sulfate Extended-Release Tablets CII	60 mg	60951-655-70
Morphine Sulfate Extended-Release Tablets CII	100 mg	60951-658-70
Morphine Sulfate Extended-Release Tablets CII	200 mg	60951-659-70
ZYDONE® (hydrocodone bitartrate/acetaminophen tablets, USP) CIII	5 mg	63481-668-70
ZYDONE® (hydrocodone bitartrate/acetaminophen tablets, USP) CIII	7.5 mg	63481-669-70
ZYDONE® (hydrocodone bitartrate/acetaminophen tablets, USP) CIII	10 mg	63481-698-70

As a brief background, production of these products has been temporarily suspended by our contract manufacturer in order for the manufacturer to implement manufacturing process improvements. These improvements are intended to address rare instances of errors in the packaging of the tablets, potentially resulting in product mix-ups. Endo is aware of only three product mix-ups with respect to these products since 2009, of which all three were detected by pharmacists. We are not aware of any patient having experienced a confirmed product mix-up and there have been no adverse events attributable to a product mix-up. We believe the likelihood of product mix-up reaching a patient is remote.



As a result of the implementation of these improvements, we anticipate that there may be a short-term disruption in the supply of these products to patients. This temporary supply disruption is not related to the efficacy or safety of these products.

Endo's principal concern is the health, well-being, and the continuity of care for those patients. In order to minimize the impact of this manufacturing issue on patients and to ensure patients are taking only the product prescribed for them, we recommend that you take the following steps:

- As a precautionary measure, as you dispense the above-listed Endo products, please open all bottles before dispensing and complete a visual inspection of the entire contents to ensure that each bottle contains the correct tablets. You can verify the appearance of these products by confirming the tablets match images in the visual guide found on www.endo.com. A copy of this visual guide is enclosed for your use.
- For any issue with either product not yet dispensed or product from a patient return, please contact Endo at 1-800-462-3636 for further information.

Please note that we have informed patients if they identify a product mix-up, they should promptly consult with you.

We are working closely with the U.S. Food and Drug Administration (FDA) and the manufacturing facility to minimize patient disruptions and our manufacturer plans to restart production of these products shortly.

We will provide you with an update on the supply status and any new developments as soon as possible. If you have any questions, please contact Endo at 1-800-462-3636.

Sincerely,

Diane K. Jorkasky, M. D., FACP
Senior Vice President Clinical Development and Chief Medical Officer